Title: Patients with established cancer cachexia lack the motivation and self-efficacy to undertake regular structured exercise.

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Compliance with Ethical Standards

Funding

This study was funded by Tenovus Cancer Care
AN's and AB's posts are fully and partially, respectively, supported by
Marie Curie core grant funding,
MCCC-FCO-14-C

Conflict of interest

The authors have full control over primary data and allow the journal to review this if requested.

Ethical Statement

The study received ethical approval from the South East Wales Ethics Committee (REC Ref 11/WA/0178) and was sponsored by Cardiff University (Ref: SPON969-11). Informed consent was obtained from all individual participants included in the study.

Acknowledgments The authors would like to thank Tenovus Cancer Care for funding the study, all the study participants who generously gave their time, and the Health and Care Research Wales workforce for their dedicated support of recruitment.

Objectives

Patients with advanced cancer frequently suffer a decline in activities associated with involuntary loss of weight and muscle mass (cachexia). This **can profoundly affect** function and quality of life. Although exercise participation can maintain physical and psychological function in patients with cancer, uptake is low in cachectic patients who are underrepresented in exercise studies. To understand how such patients' experiences **are associated with** exercise participation we investigated exercise history, self-confidence and exercise motivations in patients with established cancer cachexia, and relationships between relevant variables.

Methods

Lung and gastrointestinal cancer outpatients with established cancer cachexia (n=196) completed a questionnaire exploring exercise history and key constructs of the Theory of Planned Behaviour relating to perceived control, psychological adjustment and motivational attitudes.

Results

Patients reported low physical activity levels and few undertook regular structured exercise. Exercise self-efficacy was very low with concerns it could worsen symptoms and cause harm. Patients showed poor perceived control and a strong need for approval but received little advice from healthcare professionals. Preferences were for low intensity activities, on their own, in the home setting. Regression analysis revealed no significant factors related to the independent variables.

Conclusions

Frequently employed higher intensity, group exercise models do not address the motivational and behavioural concerns of cachectic cancer patients in this study. Developing exercise interventions which match perceived abilities and skills are required to address challenges of self-efficacy and perceived control identified. Greater engagement of health professionals with this group is required to explore potential benefits of exercise.

Background

Patients with cancer frequently suffer a decline in daily activities, associated with involuntary weight loss (in particular loss of muscle mass) and loss of appetite [1]. This syndrome of cancer-related cachexia has profound effects on quality of life (QoL) for both patients and their carers. The role of structured exercise in maintaining physical and psychological function has been explored, with improved outcomes in cachectic patients with conditions such as chronic lung disease [2], and in cancer patients undergoing active treatment [3]. There is growing evidence of its importance in cancer survivors, with ongoing research exploring the impact of exercise on cancer re-occurrence [4-6]. This data underpins the potential of exercise to reduce the rate of decline in function in more advanced disease. The non-linear relationship between muscle mass and function suggests that targeted intervention may be viable even in those with established cancer cachexia.

Nonetheless there is evidence that patients with advanced cancer engage in very low levels of physical activity [7]. To date, studies exploring the role of exercise in the advanced setting have also been small and most often in patients well enough to attend centres for group interventions. Payne's systematic review highlighted issues of attrition and poor adherence [8]. Oldervoll et al. in a randomised controlled trial of supervised exercise found that patients with incurable cancer reported high attrition particularly in those with less than one year survival, and adherence of less than 70% [9]. A pilot study of neuromuscular electrical stimulation in lung cancer patients undergoing palliative chemotherapy similarly identified adherence problems [10]. Critically, patients with established cachexia represent a minority of the participants in these studies and a Cochrane review of exercise for cancer cachexia concludes that there is insufficient evidence to determine the safety and efficacy of exercise in this patient group [11]. Studies of sufficient size and methodological quality are therefore required to formally evaluate the role of exercise in sustaining daily activities in patients with established cancer cachexia.

Successful completion of a pragmatic exercise intervention in patients with established cancer cachexia is likely to depend on the practicality, acceptability and perceived benefits of the exercise intervention [12]. The reasons for lack of engagement with physical activity in cachectic patients are not well defined, nor is it clear whether they receive any advice on exercise from their healthcare professionals. To overcome previous shortcomings and develop sustainable and clinically meaningful interventions, better understanding is therefore required of cachectic patients' beliefs around physical activity and their motivational influences.

The Theory of Planned Behaviour (TPB) proposes that patient motivation to undertake an intervention will be influenced by beliefs around expected benefit or harm (instrumental

attitudes), potential for enjoyment (affective attitudes) as well as attitudes relating to anticipated difficulty (perceived control), and sense of support and approval of others (subjective norm) [13]. There is a growing literature supporting the use of the TPB to explore exercise behaviours in cancer patients [14, 15], and encourage the promotion and sustainability of recovery in cancer survivors [16]. Although the TPB has been used to explore physical activity behaviours in a small sample of palliative cancer patients [17] it has not been formally used to explore wider patient behaviours in response to cancer related anorexia and cachexia. Nonetheless affective attitude, perceived behavioural control and subjective norm as social-cognitive constructs would appear highly relevant in examining the impact of the cancer cachexia-anorexia syndrome (CACS) on individual behaviours. The psychosocial impact of CACS is well described [17] where weight loss and change in physical appearance can prompt feelings of stigmatization and of loss of control and self-efficacy [18]. The negative impact on perceived control may be compounded by a sense of isolation [19] and conflict with the perceived expectations of family [20] and healthcare professionals [21] in relation to eating and physical activity. Use of the TPB model in a cancer cachexia population therefore offers opportunity to examine social-cognitive correlates which may have wider applicability than physical activity behaviours alone.

We have used these constructs as the basis of a study to examine how exercise history, perceived self-efficacy and attitudinal factors interact in the context of established cancer cachexia. We also wished to explore the effects of adjustment to illness and subjective norms on preferences and potential barriers to exercise, specifically in those with primary intrathoracic and gastrointestinal (GI) cancers which have a high incidence of advanced presentation and weight loss.

Methods

Participants

Between September 2011 and December 2013, 200 patients were recruited from lung cancer, GI cancer or palliative care clinics across Wales including South East, South West, Mid and North regions. Adults with lung and GI cancer with a self-reported or recorded unintentional weight loss of >5% or a BMI of <20 and any weight loss in the preceding six months were recruited from an outpatient setting. Patients fulfilling these criteria at any stage of their treatment plan were eligible. The study was approved by the South East Wales Ethics committee, and all participants gave written informed consent.

Questionnaire

The questionnaire was developed by the co-investigators and utilised items from established, validated questionnaires selected for their relevance to components of the TPB, patient health status and physical activity. Patient functional impairment was assessed using the Karnofsky Performance Status (KPS) scale which was adapted to be rated by the patients themselves [22]. The KPS is widely used in oncology and palliative care settings to quantify cancer patients' function in relation to daily activities, with a score from 100 to 0, where 100 reflects normal functioning and health. Perceived Control as a construct influences lifestyle behaviours including physical activity, exercise and health status factors [23]. This was assessed using the Thompson's nine item scale that combines Likert scales with open questions to identify any control strategies employed and their efficacy (Cronbach's α 0.69-0.88) [24, 25]. Higher values indicate more use of and efficacy of control strategies. Psychological maladjustment was assessed using the 20-point self-report scale (CES-D scale) originally developed by Radloff and widely used [26]. Irrational Beliefs, indicative of the TPB themes, were measured using the scale of Malouff and Schutte [27]. The 20-item instrument measures irrational beliefs independent of emotional reactions that might be related to those beliefs with higher values reflecting stronger perceived beliefs. The following subscales are included: Need for Approval; Need For Achievement; Demands About Others/Other Rating; Awfulizing; Emotions Are Externally Caused; Usefulness Of Being Concerned; Problem Avoidance; Importance of the Past; Demands About Life; Discomfort Anxiety. Previous work has reported good internal consistency (Cronbach's α =.80) [27].

Current confidence to exercise was assessed in three sections, firstly confidence linked directly to the illness – i.e. 'I feel confident I can exercise without making symptoms worse'. In the second and third sections, aerobic exercise (with a follow-up on intensity) and gentle resistance exercise were assessed using self-efficacy scales [28]. Current exercise behaviour was measured using two questions from the seven-day recall and lifespan exercise. These were: On how many of the last SEVEN DAYS did you participate… a) in at least 10 minutes of physical activity (e.g. gardening, cooking and walking)? b) a specific exercise session (e.g. swimming, walking, and cycling) other than what you do around the house or as part of your work? [28]. Advice from the patients' health care team was measured using a multiple response question with, for example 'Get low level exercise (such as gardening, housework) on a daily basis', available, and a free text option to describe any other exercise related advice. The perceived benefit of exercise on their condition was assessed with an 8-item scale of known links between exercise and patients with cancer. The list was derived from the ASCM literature [29] on the effects of exercise cancer and item inclusion was based on expert opinions of four of the research team. Preferences of with whom and where they would be willing to exercise were examined. Barriers to exercise were assessed using ten items specific to their condition

obtained from Sechrist, Walker [30] Examples of the items used include 'too tired', 'fear' and 'breathlessness'.

Pilot testing of the questionnaire was conducted on 15 patients with cancer. Patients in the pilot met the following criteria: clinically diagnosed with cancer, at least 18 years old, able to read, understand and give informed consent. Where appropriate revisions to the structure, response recording and administration were made. For the full study, all research nurses involved in the administration and distribution of the questionnaires were trained by one of the authors. Patients were approached in the outpatient setting. Following consent, they were given the opportunity to complete the questionnaire in the outpatient clinic or at home. **The research nurses did not record all patients approached who did not wish to take part, therefore it is not possible to report the response rate.** All questionnaires were interviewer administered with participants requesting variable degrees of support, with the duration for completion lasting up to one hour. Considering patient condition and the length of the questionnaire battery, respondents were provided the opportunity to complete it over two periods. **There were no cases of patients taking this option.**

Statistical Analysis

Descriptive results are presented as means ± standard deviation (SD), median, mode and min/max values. Analysis of data showed that the data were not normally distributed; therefore non-parametric summary data were reported. **Linear and** Logistical regression analysis **as required by the nature of the independent variable** were conducted **on the** independent variables: duration of cancer, total other conditions, **age, sex** and living alone. **These independent variables were considered for their importance in the context of cancer cachexia and relevance to exercise behaviours in other settings [14, 15, 32].** The dependent variables were general perceived control, psychological maladjustment, irrational beliefs, total barriers to exercise, total benefits of exercise and physical function.

Results

For the purposes of analysis, four participants were removed from the study due to significant levels of incomplete data. The remaining questionnaires were completed by 93 patients with GI cancer and 103 patients with lung cancer. Sample size in the analysis sections varied where items were left blank. The range is from 182 to 196 when incomplete data was present.

General participant characteristics:

The mean ±SD age of participants was 67±7 years with a 2:1 ratio of male to female respondents of whom **79% cohabited.** More than half of participants (54%) reported at least one other co-morbid condition of whom **34 had a joint related condition, 27 undergoing treatment for a heart condition, 19 had hypertension, 15 diabetes and 12 had recent**

surgery. The mean duration since diagnosis was 12.5 ±14.8 months and the distribution was positively skewed. The most commonly self-reported performance score equated to Karnofsky of 70, reflecting an inability to work, but able to live at home with no or occasional support.

Exercise history:

The majority of the study population were inactive. Historically, the level of exercise participation decreased over time as would be expected, from the first decade of adult life from a mode of 'often' (16-25; mean activity = 4.3 ±1.17 on a 5 point Likert scale) with a taper of between 0.3 and 0.5 per decade over the lifespan. Typical involvement in the last decade was rated as 'seldom' (2.5 ±1.31) in the 112 participants with complete data between the age 16 and 75.

Self-efficacy and perceived behavioural control:

General exercise over 10 minutes in duration was reported most frequently and appeared to be related to activities of daily living (ADL) rather than planned, structured exercise. Patients typically reported very low levels of self-efficacy in terms of ability to undertake either aerobic or resistance type of structured exercises with a score of 16% where 100% represents complete self-efficacy. Distributions in response to questions in relation to confidence in exercising were skewed. The median and mode values are reported (Table 1) as they reflect important information on the perceived confidence of participants. While the average response to being 'unable to exercise unless feeling like it' tends towards the middle of the scale, the mode indicated most respondents were strongly in agreement with this statement. The same pattern was observed in the question about confidence to 'exercise several times a week'.

Table 1: Confidence to exercise and amount of exercise reported

	N	Mean	SD	median	mode	Min	Max
Cannot exercise unless I feel like exercise*	196	3.90	2.00	4	6	1	6
I can exercise several times a week*	196	3.41	2.06	3	1	1	6
I feel confident I can exercise without making symptoms worse*	196	3.42	2.02	4	1	1	6
Number of days with at least 10 minutes of general exercise	192	5.02	2.76	7	7	0	7
Number of days with a specific exercise session	192	1.97	2.73	0	0	0	7

Notes: * range of response 1 (strongly disagree) - 6 (strongly agree)

There was also a trend in relation to anticipated difficulty of exercise where the majority (64%) only felt able to undertake 'light' activity rather than moderate (slightly out of breath) – 31%) -

or high (very out of breath and sweating) levels. This perception is markedly out of keeping with the moderate to high intensity levels prescribed in many current exercise studies.

More generally, the median score for perceived control over emotional and physical symptoms and relationships was 4.5 out of a maximum of 6 indicating reasonable control, although control over medical care and progression of the disease was lower (Table 2). **Linear and l**ogistical regression analysis revealed no significant factors related to the independent variables.

Table 2: Descriptive data of the key factors

Factor	N	Mean	SD	Median	Min	Max
Karnovsky*	200	66.8	10.5	70	20	80
Perceived control #						
- General Perceived control	196	4.06	1.99	4.50	0.00	6.00
- Emotional and physical symptoms	196	4.37	1.92	4.50	0.00	6.00
- Relationships	196	3.98	1.96	4.50	0.00	6.00
- Medical care	196	3.64	1.88	3.75	0.00	6.00
- Progression	196	2.25	2.15	1.75	0.00	6.00
Total Perceived control of emotional and physical symptoms^{f}	196	14.24	5.57	14.08	0.00	24.00
Psychological Maladjustment^{ff}	196	14.88	10.50	13.00	0.00	52.00
Irrational beliefs – Total ¥	186	57.82	16.01	57.50	23.00	94.00
- Need for approval ¥¥	195	6.48	2.61	6.00	2.00	10.00
- Need for achievement	195	5.77	2.72	6.00	2.00	10.00
- Demands about others	188	4.20	2.61	3.00	2.00	10.00
- Awfulizing	195	5.07	2.49	5.00	2.00	10.00
- Emotions are externally caused	194	5.37	2.38	5.00	2.00	10.00
- Usefulness of being concerned	195	7.10	2.37	8.00	2.00	10.00
- Problem avoidance	195	4.56	2.19	5.00	2.00	10.00
- Importance of the past	195	6.27	2.70	6.00	2.00	10.00
- Demands about life	194	6.20	2.72	6.00	2.00	10.00
- Discomfort anxiety	194	6.67	2.70	7.00	2.00	10.00

Notes: * = range 20 (limited daily living function) to 80 (high daily living function); # = range 0 (no control and not effective) – 6 (high control and effective); *f* = range 0 (no control and not effective) – 24 (high control and effective); *ff* = range 0 (low maladjustment) – 52 (high maladjustment); ¥ = range 23 (low) – 94 (high);; ¥¥ = range 2 (strongly disagree) – 10 (strongly agree).

Expected benefits, perceived barriers and approval of others:

Participants were asked several questions in relation to the perceived effects of exercise on their cancer and symptoms. They expressed strong reservations about the statement relating to ‘exercise not making symptoms worse’. In keeping with concerns that exercise might negatively affect symptoms, only a minority of patients felt that structured exercise would reduce the effects of their cancer. This resonates with their low perceived control over their illness. The most common perceived benefits of exercise related to improvements in mood, appetite and cognition (Table 3). Although participants identified a strong need for approval,

they reported receiving very limited exercise advice from healthcare professionals, with 69% of patients reporting receiving no advice at all. Those who did get advice were typically told to do low intensity exercise.

In keeping with participant concerns of negative effects on symptoms and perceived difficulty, the most commonly perceived barriers to exercising were symptoms of fatigue (n=99, 51%), breathlessness (n=76, 39%) and the presence of other health conditions.

Table 3 summarises preferences for place of exercise, and with whom participants would like to undertake structured activity. In keeping with previous reports[31], the majority wished to undertake exercise at home rather than in institutional settings or with other patients. Although 31% of participants would be happy to exercise with partners or friends, the preferred option was to exercise alone, despite concerns over symptoms and their low perceived self-efficacy with all exercise types.

Table 3: Perceived benefits and location and social factors of exercise preferences

Factor	Item	No	Yes	% Yes
Benefit of PA*	Limit the effect of cancer	141	55	28
	Think better	72	124	63
	Stay more alert	67	129	66
	Improve mood	66	130	66
	Help socialize	92	104	53
	Improve appetite	67	129	66
	Help me do/maintain tasks	59	137	70
Location Preference*	At home	44	152	78
	Fitness centre	170	26	13
	Hospital	170	26	13
	Day centre	173	24	12
	Community Hall	176	20	10
With Whom*	Other patients	155	41	21
	Friends	134	62	32
	On my own	75	121	62
Barriers#	No point	183	12	6
	Family concern	176	19	10
	Afraid	168	27	14
	Would be tiring	96	99	51
	Too expensive	184	11	6
	Too much pain	144	51	26
	Too tired	99	96	49
	Out of breath	119	76	39
	Don't know where to	186	9	5
	No transport	186	9	5
	Don't like	174	21	11

Note: * n = 196; # n = 195

Discussion

This questionnaire study uniquely captures information on the attitudes and perceived control which influence motivation to exercise in a large cohort with established cancer cachexia. The importance of instrumental and affective attitudes on exercise participation has previously been described in cancer patients [32], but their nature and strength in the cachectic population has not previously been explored in detail.

Our study was undertaken with 200 lung and upper GI patients. Despite the presence of cachexia they described themselves as largely independent and able to self-care. Yet as a group they are significantly under-represented in published studies, and even in palliative contexts interventions are being increasingly targeted at earlier stages of the patient pathway [9]. Understanding the desirability of physical activity, and what influences the strength of patients' intention to undertake exercise, will guide clinical practice in helping to maintain independence and inform the design of future studies in this patient group.

Our results demonstrate a lack of self confidence in the ability to undertake exercise and a strong belief that even moderate intensity exercise would be too difficult. This is reflected in an exercise history which declines consistently from the first adult decade to a point where the majority describe only low levels of informal activity.

The lack of perceived control is compounded by concerns that regular exercise could make symptoms worse and a lack of belief that it would positively influence the course of their cancer. Although approval of others also appears to be an important concept for this patient group, the majority would prefer to undertake exercise at home and alone. All of this contrasts with common intervention designs in cancer studies, which tend towards group based and at least moderate intensity interventions [9, 33] and underscores the challenges for tailoring regimens to the individual, as advised in American College of Sports Medicine Guidelines [34].

Clinical implications

Our results highlight key elements which need to be addressed to improve participation in exercise activities as part of clinical care, with important lessons also for the design of studies involving this particular patient group. Firstly, the perceived lack of benefit of exercise and concerns regarding harm require engagement from healthcare professionals. Tellingly, most participants (69%) reported receiving no advice on exercise from their clinicians. In a UK study Williams et al. surveyed 460 multi-professional cancer clinicians and found that they offered lifestyle advice to less than 50% of their patients [35]. Puhringer et al. identified several barriers for clinicians including lack of expertise, time and support infrastructure [21]. Although lack of robust data supporting benefits of exercise in the cachectic cancer patient is likely to impact on clinician behaviours, focused education on the wider potential of planned exercise activities

to improve outcomes [36, 37], and on identifying the specific concerns of this patient group, may help empower individual patients to engage [38].

Secondly, self-efficacy has been shown to be a stronger predictor of physical activity in cancer patients [39]. Direct involvement of patients in co-production of planned, structured exercise activities is required to address the attitudinal and self-efficacy challenges described. Studies in other conditions have suggested that patients are more likely to engage in interventions which match their previous skills and abilities and minimise disruption to daily life [40]. Our patient group indicated a preference for low intensity activity which may explain poor adherence to institutionally based, moderate intensity, group exercise [9]. Identifying interventions of lower intensity, which relate more to activities of daily living and build on previous abilities would positively impact on perceived control, associated with a greater chance of achieving behaviour change [41]. This may inform the goals and outcome measures which are of most relevance to participants. Thirdly, more understanding is required of the type of supervision most likely to support adherence in clinical and research contexts. Identifying the type of instructional content and feedback that would enable, strengthen and/or maintain exercise intent is required, balanced against the desire for privacy and home based approaches. Fourthly, our results highlight the importance of prior understanding of the beliefs influencing exercise preferences in cancer cachexia in allowing comparison between randomised groups within research studies. This may help minimise bias as previously described in other settings [32].

Limitations

The strengths of our study include the recruitment of a large participant group with established unintended weight loss across different geographical settings, and the use of validated questionnaires reflecting a validated theoretical model of understanding patient preferences. The limitations of the study include the cross-sectional nature with the inclusion of patients at varied stages of treatment, using responses based on patient recall, and use of a researcher-administered questionnaire set which might influence responses.

Conclusion

In summary, this study of 196 evaluable patients with cancer cachexia demonstrates the significant concerns they have in relation to the impact of exercise on both symptoms and their cancer, and their low levels of confidence and self-efficacy in relation to structured exercise. Compounding this is a lack of advice and empowerment from their healthcare providers. This may help explain why patients with established cancer cachexia are under-represented in studies of exercise interventions, frustrating attempts to address clinical uncertainty on the**ir** effects in this patient group. These findings have important implications for clinical practice

and for future research designs, making common models of exercise in group settings difficult to realise in this population group. We suggest a more consistent approach to involving patients with established cachexia in exercise studies, with a greater emphasis for that subgroup on patient designed, structured activity models which address the specific attitudinal and self-efficacy concerns highlighted here.

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